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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/810,385   | 03/16/2001  | Allen S. Laughon     | WARF-0002           | 8778             |
| 26259  | 7590        | 09/12/2005           | EXAMINER            |                  |
| LICATLA & TYRRELL P.C.<br>66 E. MAIN STREET<br>MARLTON, NJ 08053 |             |                      | HARRIS, ALANA M     |                  |
|  |             | ART UNIT             | PAPER NUMBER        |                  |
|  |             | 1643                 |                     |                  |

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/810,385             | LAUGHON, ALLEN S.   |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Alana M. Harris, Ph.D. | 1643                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 04/25/05.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-4 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-4 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment and Arguments***

1. Claims 1-4 are pending.  
Claims 1, 2 and 4 have been amended.  
Claims 1-4 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Maintained Rejections and New Grounds of Rejections***

#### ***Claim Rejections - 35 USC § 112***

4. The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained and newly made. **THIS IS A NEW MATTER REJECTION.**

Applicant has amended claim 1 to include the recitations, "TGF- $\beta$  - dependent promoter..." and "expressing interacting proteins...". Furthermore, claim 2 has been amended to include the recitation "...expressing a Smad protein...".

Applicant asserts the specification provides support for the claimed method including a Smad protein co-repressor, as well as the contemplation of interacting

proteins. Applicant relies on the MPEP stating, "claimed subject matter need not be described literally..." and passages within the specification (see page 7, lines 17 and 18; page 14, lines 11-21) as support for the claims. The specification and these arguments submitted November 10, 2004 have been carefully considered, but found partially persuasive.

Applicant has pointed out several passages within their specification where they believe support for the questioned recitations and claimed methodology is listed. After review of the specific passages within the specification the Examiner does not concur. On page 7, lines 17 and 18 it is clear that Schnurri is a co-repressor, as well as the other DNA-bind Smad co-repressors (Evi-1, TGIF and SIP1). The Examiner does not refute that fact, however this section of the specification does not support the claimed method including cells containing interacting proteins comprising a Smad protein, a DNA-binding Smad co-repressor protein and a CtBP protein and the detection steps. The rejection set forth in the Action mailed August 10, 2004 makes note that Applicant has pointed out scientific observations such as that listed on page 7, but this does not exemplify an experimental design of the claimed assay. The steps listed in the claims are not of record in the specification.

Moreover, while it is true that the claimed subject matter need not be described literally it should be of record in the specification with the specific teachings as set forth in the claims. Namely at page 14, lines 11-21 there is the prophetic teaching that assays *can be* developed that interact with Smad protein to prevent interaction of CtBP with Smads or DNA-binding co-repressors or that interrupt the formation of a DNA-

bound complex containing Smads, CtBP and DNA-binding co-repressors, however this is not support for the claims specifically setting forth a method. The claims do not meet the written description requirement because the specification is remiss of active method steps including the cells containing interacting proteins and compounds necessitated for implementing the claimed method.

The amendments including the reporter and Smad-box containing promoter are not supported by the specification. Applicant directs the Examiner's attention to the paragraph bridging pages 14 and 15, however this section does list the reporter with a Smad box-containing promoter within cells containing specifically interacting proteins with the detection of transcription and the comparison between levels of transcription at precise points. Applicant has not pointed out where in the specification where these precise words or similar language are found in the context of the claimed method and its steps. Applicant is requested to pointedly express where support can be found or delete the new matter at which time the 102(a) rejection set forth in the first action on the merits (FAOM), mailed May 6, 2003 may be reinstated. Applicant may obviate the instant rejection by concisely and precisely establishing claims inclusive of claim language, active steps and necessitated compounds fully of record in the specification.

5. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

Applicant argues the instant disclosure reveals target genes and functional mammalian homologues of dCtBP are well known in the art. Applicant further notes that the essential features of the claimed method were individually known, however not in association with the instantly claimed method. These points of view have been carefully considered but found unpersuasive.

Applicant has amended claims to include mammalian homologue of CtBP, however this amendment does not aid in obviating the instant rejection. There is essentially no guidance assuring one of ordinary skill in the art that these homologues would share structure, which germane to the method claimed. Moreover, there is insufficient evidence that the structure is associated with function, which is essential to the method.

And while Applicant notes target genes that are under the influence of negative regulation by TGF-B, BMP, etc. this list does not preclude other undiscovered genes nor read on those genes under positive influence of these regulators. The disclosure of some of the target genes is not a representative number of species. This set of species is an inverse function of the skill and knowledge in the art and while some of the species are known this invention is in an unpredictable art and adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing some of the genus. The written description in this instant case only sets forth wild type dCtBP, see figure descriptions on pages 5 and 6 and does not disclose the plethora of genes that may be induced by TGF- $\beta$ , activin or bone morphogenetic protein. The written description is not commensurate in scope with claims drawn to a method

With the exception of wild-type dCtBP, the skilled artisan cannot envision the detailed structure or function of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Likewise, the skilled artisan cannot envision the detailed structure or function of the plethora of genes that may be induced by three distinct proteins. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptides and molecules germane to the methodology itself are required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

At the time the application was filed Applicants only had possession of dCtBP and not polypeptides that may or may not act in the manner suggested by the

specification. The specification does not evidence the possession of all functional dCtBP molecules. Nor does the specification teach any genes that are induced by the three divergent molecules, TGF- $\beta$ , activin or bone morphogenetic protein. There is insufficient support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ALANA M. HARRIS, PH.D.**

**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.

25 July 2005